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mt	57	ZELLER et al.	ZELLER et al., "Induction of CD4+ T Cell Alloantigen-Specific Hyporesponsiveness by IL-10 and TGF-β¹, <i>Journal of mmunology</i> 163:3684-3691 (1999)							
mH	58	BOUSSIOTIS	, "Altered T-cing growth fa	eli receptor +	CD28-mediated singnali alloreactive T cells that					
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HADDAD, Maher M.

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September 1, 2000

HORWITZ, David A.

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**Filing Date** 

Group Art Unit

**Application Number** 

**First Named Inventor** 

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**Examiner Name** HADDAD, Maher M. Sheet

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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>					
MH	61	ASANO M, et al., "Autoimmune disease as a consequence of developmental abnormality of a T cell subpopulation." J Exp Med. 1996 Aug 1;184(2):387-96.						
,	62	AUCHINCLOSS, Hugh Jr., et al, in Fundamental Immunology 4th Ed., Paul, W.E. (ed.) Lippincot-Raven: Philadelphia New York; 1999 pp. 1182-1222.						
	BETZ, M. and FOX, B.S., "Prostaglandin E2 inhibits production of Th1 lymphokines but not of Th2 lymphokines," J Immunol. 1991 Jan 1;146(1):108-13.							
	64	BONIG H, et al., "Transforming growth factor-beta1 suppresses interleukin-15-mediated interferon-gamma production human T lymphocytes." Scand J Immunol. 1999 Dec;50(6):612-8.	AUG 1					
	65	BUCY, R.P. et al., FASEB J. 1995 9:A497 (Abstract)	4 2002					
	CHANDRASEKAR, B., et al., "Dietary calorie restriction inhibits transforming growth factor-beta (TGF- beta) express in murine lupus nephritis", 9th International Congress on Immunology, 848 (1995)  CHONG P. et al. "Inhibition of protein-kinase C in peripheral blood mononuclear cells of patients with systemic lupus erythematosus: effect on spontaneous immunoglobulin production," Autoimmunity, 10:227-231 (1991)							
	68	COSIMI, A.B., et al., "Treatment of acute renal allograft rejection with OKT3 monoclonal antibody," Transplantation. 1981 Dec;32(6):535-9.						
	69	DELGIUDICE, G., et al., "TGF-beta activity is increased in systemic lupus erythematosus (SLE) and progressive systemic sclerosis (PSS)", Arthritis and Rheumatism Vol. 36 (9 Suppl.) p S196(Sept. 1993)						
	70	DOOMS, H. et al., "IL-2 and IL-15 direct the outcome of inappropriate CD4+ T cell stimulation towards apoptosis and anergy respectively," European Cytokine Network, 9(3):169 (1998)						
	71	FERNANDES, G., et al., "Calorie restriction delays autoimmune murine lupus by differentially modulating oncogenes and TGF- beta-1 expression", 9th International Congress on Immunology., 848 (1995).						
	72	GAO Q, et al., "CD4+CD25+ cells regulate CD8 cell anergy in neonatal tolerant mice." Transplantation. 1999 Dec 27;68(12):1891-7.						
	73	GRAY et al., "Activated Natural Killer Cells Can Induce Resting B Cells to Produce Immunoglobulin," Arthritis & Rheumatism, 37(9)suppl:S378 (1994)						
	74	GRAY, J. D., et al., "Generation of an Inhibitory Circuit Involving CD8+ T Cells, IL-2, and NK Cell-Derived TGF-β: Contrasting Effects of Anti-CD2 and Anti-CD3", Journal of Immunol., 160:2248-2254 (1998).						
	75	GROUX, H., et al., "A CD4+ T-cell subset inhibits antigen-specific T-cell responses and prevents colitis," Nature. 1997 Oct 16;389(6652):737-42.						
	76	HAHN, B.H., Dubois'Lupus Erythematosus, 5th Ed. (1997), pp. 69-76 (D.J. Wallace et al. eds., Williams and Wilkins, Baltimore)						
	77	HORWITZ DA, et al., "Decreased production of interleukin-12 and other Th1-type cytokines in patients with recent-onset systemic lupus erythematosus." Arthritis Rheum. 1998 May;41(5):838-44.						
V	78	HORWITZ, D. A., et al., "The immunoregulatory effects of NK cells: the role of TGF-β and implications for autoimmunity", Immunology Today, Vol. 18(11):538-542 (Nov. 1997).						
MH	79	HORWITZ, D.A., Dubois'Lupus Erythematosus, 5th Ed. (1997), pp. 155-194 (D.J. Wallace et al. eds., Williams and Wilkins, Baltimore)						

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Sheet 5

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Application Number	09/653,924	7
Filing Date	September 1, 2000	7
First Named Inventor	HORWITZ, David A.	Ali6 1 2 2002
Group Art Unit	1644	2
Examiner Name	HADDAD, Maher M.	TEL S
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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
mH 80		HUGGINS, M. L., et al., "Modulation of the Autoimmune Response in Lupus Mice by Oral Administration of Attenuated Salmonella typhimurium Expressing the IL-2 and TGF-β Genes", Annals of New York Acad. of Sciences, Vol. 815:499-502 (1997)	
3	81	JACKSON AL, et al., "Restricted expression of p55 interleukin 2 receptor (CD25) on normal T cells." Clin Immunol Immunopathol. 1990 Jan;54(1):126-33.	
	82	JONULEIT, H., et al., "Induction of interleukin 10-producing, nonproliferating CD4(+) T cells with regulatory properties by repetitive stimulation with allogeneic immature human dendritic cells," J Exp Med. 2000 Nov 6;192(9):1213-22.	
	83	KANEGANE H, et al., "A novel subpopulation of CD45RA+ CD4+ T cells expressing IL-2 receptor alpha-chain (CD25) and having a functionally transitional nature into memory cells." Int Immunol. 1991 Dec;3(12):1349-56.	
	84	KIRK, A.D., et al., "CTLA4-Ig and anti-CD40 ligand prevent renal allograft rejection in primates," Proc Natl Acad Sci U S A. 1997 Aug 5;94(16):8789-94.	
	85	KLINMAN DM, et al., "Quantitation of IgM- and IgG-secreting B cells in the peripheral blood of patients with system lupus erythematosus." Arthritis Rheum. 1991 Nov;34(11):1404-10.	P
	86	KOIDE, J. and ENGLEMAN, E.G., "Differences in surface phenotype and mechanism of action between alloantige specific CD8+ cytotoxic and suppressor T cell clones," J Immunol. 1990 Jan 1;144(1):32-40.	AUG
	87	LANCASTER, F., et al., "Anti-idiotypic T cells suppress rejection of renal allografts in rats," Nature. 1985 May 23-29;315(6017):336-7.	4
	88	LANGREHR, J.M., et al., "Evidence that nitric oxide production by in vivo allosensitized cells inhibits the development of allospecific CTL," Transplantation. 1992 Mar;53(3):632-40.	2002
	89	LARSEN, C.P., et al., "Long-term acceptance of skin and cardiac allografts after blocking CD40 and CD28 pathway Nature. 1996 May 30;381(6581):434-8.	
	90	LINKER-ISRAELI M, et al., "CD8+ lymphocytes from patients with systemic lupus erythematosus sustain, rather than suppress, spontaneous polyclonal IgG production and synergize with CD4+ cells to support autoantibody synthesis." Arthritis Rheum. 1990 Aug;33(8):1216-25.	
L _	91	MASSAGUE J., "The transforming growth factor-beta family." Annu Rev Cell Biol. 1990;6:597-641.	
	92	MIZUOCHI, T., et al., "Both L3T4+ and Lyt-2+ helper T cells initiate cytotoxic T lymphocyte responses against allogenic major histocompatibility antigens but not against trinitrophenyl-modified self," J Exp Med. 1985 Aug 1;162(2):427-43.	
	93	MYSLIWIETZ J and THIERFELDER S., "Antilymphocytic antibodies and marrow transplantation. XII. Suppression of graft-versus-host disease by T-cell-modulating and depleting antimouse CD3 antibody is most effective when preinjected in the marrow recipient." Blood. 1992 Nov 15;80(10):2661-7 (Abstract)	
	94	OHTSUKA, K., et al., "Decreased Production of TGF-β by Lymphocytes from Patients with Systemic Lupus Erythematosus", J. Immunol. 160:2539-2545 (1998).	
*	95	PAPIERNIK M, et al., "T cell deletion induced by chronic infection with mouse mammary tumor virus spares a CD25-positive, IL-10-producing T cell population with infectious capacity." J Immunol. 1997 May 15;158(10):4642-53.	
WIT	96	PEARCE, N.W., et al., "Specific unresponsiveness in rats with prolonged cardiac allograft survival after treatment with cyclosporine. V. Dependence of CD4+ suppressor cells on the presence of alloantigen and cytokines, including interleukin 2," Transplantation. 1993 Feb;55(2):374-80.	

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Complete if Known Substitute for form 1449B/PTO **Application Number** 09/653,924 INFORMATION DISCLOSURE Filing Date September 1, 2000 <del>Aŭ6</del> 1 2 20 STATEMENT BY APPLICANT **First Named Inventor** HORWITZ, David A Group Art Unit (use as many sheets as necessary) **Examiner Name** HADDAD, Maher M. RADEN Attorney Docket Number A-67689-3/RFT/RMS/RMK of Sheet

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
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Hm'	97	PESCOVITZ, M.D., et al., "Effect of class II antigen matching on renal allograft survival in miniature swine," J Exp Med. 1984 Nov 1;160(5):1495-508.QIN, L., et al., "Gene transfer for transplantation. Prolongation of allograft survival with transforming growth factor-beta 1," Ann Surg. 1994 Oct;220(4):508-18; discussion 518-9.	
)	98	POWRIE F, et al., "A critical role for transforming growth factor-beta but not interleukin 4 in the suppression of T helper type 1-mediated colitis by CD45RB(low) CD4+ T cells." J Exp Med. 1996 Jun 1;183(6):2669-74.	
	99	QIN, L., et al., "Gene transfer for transplantation. Prolongation of allograft survival with transforming growth factor-beta 1," Ann Surg. 1994 Oct;220(4):508-18; discussion 518-9	
	100	QIN, L., et al., "Retrovirus-mediated transfer of viral IL-10 gene prolongs murine cardiac allograft survival," J Immunol. 1996 Mar 15;156(6):2316-23.	
	101	RAJU, G.P., et al., "Prolongation of cardiac allograft survival with transforming growth factor-beta 1 in rats," Transplantation. 1994 Aug 15;58(3):392-6.	
	102	RAMSDELL, F. and FOWLKES, B.J., "Maintenance of in vivo tolerance by persistence of antigen," Science. 1992 Aug 21;257(5073):1130-4.	
	103	READ S, et al., "Cytotoxic T lymphocyte-associated antigen 4 plays an essential role in the function of CD25(+)CD4(+) regulatory cells that control intestinal inflammation." J Exp Med. 2000 Jul 17;192(2):295-302.	
	104	ROCHA, B., et al., "Clonal anergy blocks in vivo growth of mature T cells and can be reversed in the absence of antigen," J Exp Med. 1993 May 1;177(5):1517-21.	
	105	ROSER, B.J., "Cellular mechanisms in neonatal and adult tolerance," Immunol Rev. 1989 Feb;107:179-202.	T
	106	SAKAGUCHI S, et al., "Organ-specific autoimmune diseases induced in mice by elimination of T cell subset. I. Evidence for the active participation of T cells in natural self-tolerance; deficit of a T cell subset as a possible cause of autoimmune disease." J Exp Med. 1985 Jan 1;161(1):72-87.	
	107	SAKAGUCHI, S., et al., "Immunologic self-tolerance maintained by activated T cells expressing IL-2 receptor alphachains (CD25). Breakdown of a single mechanism of self-tolerance causes various autoimmune diseases," J Immun 1995 Aug 1;155(3):1151-64.	
	108	SEDDON, B. and MASON, D., "The third function of the thymus," Immunol Today. 2000 Feb;21(2):95-9.  SHEVACH, E.M., "Regulatory T cells in autoimmmunity," Annu Rev Immunol. 2000;18:423-49.	
T	109	SHEVACH, E.M., "Regulatory T cells in autoimmmunity," Annu Rev Immunol. 2000;18:423-49.	
	110	SHIVAKUMAR S, et al., "T cell receptor alpha/beta expressing double-negative (CD4-/CD8-) and CD4+ T helper cells in humans augment the production of pathogenic anti-DNA autoantibodies associated with lupus nephritis." J Immunol. 1989 Jul 1;143(1):103-12.	
	111	SINGER, A., et al., "Self recognition in allogeneic radiation bone marrow chimeras. A radiation-resistant host element dictates the self specificity and immune response gene phenotype of T-helper cells," J Exp Med. 1981 May 1;153(5):1286-301.	
100	112	SNIJDEWINT, F.G., et al., "Prostaglandin E2 differentially modulates cytokine secretion profiles of human T helper lymphocytes," J Immunol. 1993 Jun 15;150(12):5321-9.	
mH	113	STARZL, T.E., et al., "Chimerism and donor-specific nonreactivity 27 to 29 years after kidney allotransplantation," Transplantation. 1993 Jun;55(6):1272-7.	

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Examiner Cite No.		item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						
, mH	114	STRAND, V., "Approaches to the management of systemic lupus erythematosus," Current Opinion in Rheumatology, 9:410-420 (1997)						
	115	SURI-PAYER E, et al., "CD4+CD25+ T cells inhibit both the induction and effector function of autoreactive T cells and represent a unique lineage of immunoregulatory cells." J Immunol. 1998 Feb 1;160(3):1212-8.						
116		SURI-PAYER E, et al., "Post-thymectomy autoimmune gastritis: fine specificity and pathogenicity of anti-H/K ATPase-reactive T cells." Eur J Immunol. 1999 Feb;29(2):669-77.						
	117	TAAMS, L.S., et al., "Anergic T cells actively suppress T cell responses via the antigen-presenting cell," Eur J Immunol. 1998 Sep;28(9):2902-12.						
	118	TAKAHASHI T, et al., "Human CD8+ lymphocytes stimulated in the absence of CD4+ cells enhance IgG production by antibody-secreting B cells." Clin Immunol Immunopathol. 1991 Mar;58(3):352-65.						
	119	TAKAHASHI T, et al., "Immunologic self-tolerance maintained by CD25+CD4+ naturally anergic and suppressive T calls: induction of autoimmune disease by breaking their anergic/suppressive state." Int Immunol. 1998 Dec;10(12):1969-46.						
	120	THORNTON AM and SHEVACH EM. "CD4+CD25+ immunoregulatory T cells suppress polyclonal T cell activation vitro by inhibiting interleukin 2 production." J Exp Med. 1998 Jul 20;188(2):287-96.	A					
	121	THORNTON AM and SHEVACH EM. "Suppressor effector function of CD4+CD25+ immunoregulatory T cells is artisen nonspecific." J Immunol. 2000 Jan 1;164(1):183-90.	<b>U</b> 6 1					
	122	TOMITA, Y., et al., "Importance of suppressor T cells in cyclophosphamide-induced tolerance to the non-H-2-encoded alloantigens. Is mixed chimerism really required in maintaining a skin allograft tolerance?" J Immunol. 1990 Jan 15;144(2):463-73.	<b>♣</b> 2002					
	123	VENDETTI, S., et al., "Anergic T cells inhibit the antigen-presenting function of dendritic cells," J Immunol. 2000 Aug 1;165(3):1175-81.	22					
124		VERBANAC, K.M., et al., "A role for transforming growth factor-beta in the veto mechanism in transplant tolerance, Transplantation. 1994 Mar 27;57(6):893-900.						
125		WAHL SM. "Transforming growth factor beta: the good, the bad, and the ugly." J Exp Med. 1994 Nov 1;180(5):1587-90.						
	126	WEKERLE, T., et al., "Anti-CD154 or CTLA4lg obviates the need for thymic irradiation in a non-myeloablative conditioning regimen for the induction of mixed hematopoietic chimerism and tolerance," Transplantation. 1999 Nov 15;68(9):1348-55.						
	127	WEINER HL, et al., "Oral tolerance: immunologic mechanisms and treatment of animal and human organ-specific autoimmune diseases by oral administration of autoantigens." Annu Rev Immunol. 1994;12:809-37						
	128	WILSON, D.B., "Idiotypic regulation of T cells in graft-versus-host disease and autoimmunity," Immunol Rev. 1989 Feb;107:159-77.						
	129	ZHENG, X.X., et al., "Administration of noncytolytic IL-10/Fc in murine models of lipopolysaccharide-induced septic shock and allogeneic islet transplantation," J Immunol. 1995 May 15;154(10):5590-600.						
4	130	MARTIN, P.J. et al., "Treatment of Acute Graft-Versus-Host Disease with Anti-CD3 Monoclonal Antibodies," Am Jour Kidney Disease 11(2):149-152 (1988)						
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INFORMATION DISCLOSURE CITATION					ATTY. DOCKET NO. A-67689-3/RFT/RMS/R	SERIAL NO. 09/653,924				
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EXAMINER'S INITIALS		PATENT NO.	DATE		COUNTRY	CL	ASS	SUBCLASS	Trans Yes	No
MH	1.	93/17698	9/1993	PCT (WO)		_				
mH	2.	97/42324	11/1997	PCT (WO)		_				
MH	3	99/25366	5/1999	PCT (WO)						
	0	THER DOC	UMENTS	(Including	Author, Title, Date	e, Pe	ertine	ent Pages	, Etc.)	
MH	4.	Martin, "Overview of Marrow Transplantation Immunology", in Bone Marrow Transplantation (eds. Forman et al.) pp. 16-21, Boston, <i>Blackwell Scientific Publications</i> (1994)								
MA	5.	Dupont, B., "Immunology of hematopoietic stem cell transplantation: a brief review of its history", <i>Immunol Reviews</i> 157:5-12 (1997)								
MIT	6.	Rodt, H., "Anti-lymphocytic antibodies and marrow transplantation. 3. Effect of heterologous anti-brain antibodies on acute secondary disease in mice", Eur. J. Immunol 4:25-29 (1974)								
EXAMINER	Mahn Haddad DATE CONSIDERED 9/16/02									

INFO	2N/1	ATION DISCLOSURE	ATTY. DOCKET NO. A-67689-3/RFT/RMS/RMK	SERIAL NO. 09/653,924			
CITATION APPLICANT  JAN 1 6 2001 HORWITZ							
		PTO-1449	FILING DATE September 1, 2000	GROUP Not Yet Assigned			
	ГО	THER DOCUMENTS THE HELDER	Author, Title, Date, Pe	rtinent Pages, Etc.)			
7. Vallera et al., "Bone marrow transplantation across major histocompatibility barriers in mice. E elimination of T cells from donor grafts by treatment with monoclonal Thy-1.2 plus complemen alone", <i>Transplantation</i> 31:218-222 (1981)							
	8.	Martin et al., "Effects of in vitro deple 66:664-672 (1985)	etion of T cells in HLA-identical	allogeneic marrow grafts", <i>Blood</i>			
	9.	Patterson et al., "Graft rejection follow transplantation", <i>Br J Haematol</i> 63:22		yte depleted bone marrow			
	10.	Goldman et al., "Bone marrow transp Increased risk for relapse associated					
	11.	Lucas et al., "The development of ce transplantation", Blood 87:2594-2603		virus after allogeneic bone marrow			
	12.	Blazar et al., "FK506 inhibits graft-ve recipients of MHC disparate donor gransplantation", <i>J. Immunol</i> 153:183	rafts by interfering with mature				
	13. Blazar et al., "Murine recipients of fully mismatched donor marrow are protected form lethal graft-versus-host disease by the in vivo administration of rapamycin but develop an autoimmune-like syndrome", <i>J. Immunol</i> 151:5726-5741 (1993)						
	14.	Dumont et al., "Distinct Mechanisms FK-506 and Rapamycin", J. Immuno.		ell Activation by the Related macrolides			
	15. Morris, "Prevention and treatment of allograft rejection in vivo by rapamycin: molecular and celular mechanisms of action", <i>Ann NY Acad Sci</i> 685:68-72 (1993)						
	16.	Gratama et al., "Treatment of Acute of results and effect on circulating T lyn		ith Monoclonal Antibody OKT3. Clinical 8(5):469-474 (1984)			
	17.	Hiruma et al., "Effects of anti-CD3 me allografts in mice: host T-cell suppre					
	18.	Anasetti et al., "Treatment of acute g antibody", <i>Transplantation</i> 54:844-85		a nonmitogenic anti-CD3 monoclonal			
	19.	Martin et al., "Effects of treating marr versus-host disease", Bone Marrow	Transplant 3:437-444 (1989)				
	20. Herve et al., "Treatment of Corticosteroid Resistant Acute Graft-Versus-Host Disease by In Vivo Administration of Anti-Interleukin-2 Receptor Monoclonal Antibody (B-B10)", <i>Blood</i> 75(4):1017-1023 (1990)						
	21.	Boussiotis et al., "B7 but not intercell human alloantigen-specif tolerance,"					
	22. Gribben et al., "Complete blockade of B7 family-mediated costimulation is necessary to induce human alloantigen-specific anergy: a method to ameliorate graft-versus-host disease and extend the donor pool", Blood 97:4887-4893 (1996)						
23. Blazar et al., "Recent advances in graft-versus-host disease (GVHD)", Immunol Rev 157:79-90 (1997							
WH 24. Krenger et al., "Effects of exogenous interleukin-10 in a murine model of graft-versus-host disease to minor histocompatibility antigens", <i>Transplantation</i> 58:1251-1257 (1994)							
EXAMINER Maher Haddad DATE CONSIDERED 9/16/02							

INICORMATION DISCEMBEIDE			ATION DICCEOPERE	ATTY. DOCKET NO. A-67689-3/RFT/RMS/RMK	SERIAL NO. 09/653,924			
INFORMATION DISCLOSURE CITATION				APPLICANT HORWITZ				
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		ТО	THER DOCUMENTS Anchoring A	Author, Title, Date, Pe	rtinent Pages, Etc.)			
M	(+	25.		Cells Can Cause Accelerated GVHD Lethality in the Presence of D: Role of Interfereon Gamma (IFNy) in GVHD Induction, Blood				
		26.	Krenger et al., "Polarized type 2 allorea acute graft-versus-host disease", J Imr.		or T cells fail to induce experimental			
		27.	Fowler et al., "Donor CD4-enriched cell without impairing allogeneic engraftment					
		28.	Bonini et al., "HSY-TK gene transfer int leukemia, Science 276:1719-1724 (199		ntrol of allogeneic graft-versus-			
		29.	Storb et al., "Long-term follow-up of a c cyclosporine with cyclosporine alone fo HLA-identical marrow grafts for leukem	or prophylaxis of graft-versus	s-host disease in patients administered			
		30.	Sullivan et al., "Chronic Graft-Versus-H Transplantation", Semin Hematol 28:25		Complications of Bone Marrow			
		31.	Via et al., "Critical Role of interleukin-2 International Immunol 5:565-572 (1993	•	graft-versus-host disease",			
		32.	Fast, "Generation and characterization of IL-2-activated veto cells", J Immunol 149:1510-1515 (1992)					
		33.	Hirohata et al., "Role of II-2 in the gene Immunol 142:3104-3112 (1989)	ration of CD4+ suppressors	of human B cell responsiveness", J			
		34.	Taylor, "Antigen specific suppressor T Biol 319:125-135 (1992)	cells respond to cytokines re	eleased by T cells", Advances Exp Med			
		35.	Kinter et al., "Interleukin 2 induces CD8+ T cell-mediated suppression of human immunodeficiency virus replication in CD4+ T cells and this effect overrides its ability to sitmulate virus expression", <i>Proc. Natl. Acad. Sci. USA</i> 92:10985-10989 (1995)					
		36. Barker et al., "Identification of multiple and distinct CD8+ T cell suppressor activities: dichotomy between infected and uninfected individuals, evolution with progression of disease, and sensitivity to gamma irradiation," <i>J Immunol</i> 156:4476-4483 (1996)						
		37.	Hirokawa et al., "Human resting B lymphocytes can serve as accessory cells for anti-CD2-induced T cell activation", <i>J. Immunol.</i> 149:1859-1866, 1992					
		38.	Border et al., "Transforming growth factor-beta in disease: the dark side of tissue repair," <i>J Clin Invest</i> 90:1-7 (1992)					
		39.	Sporn et al., "Some recent advances in the chemistry and biology of transforming growth factor-beta," <i>J Cell Biol</i> 105:1039-1045 (1987)					
		40.	Massague, "Receptors for the TGF-bata family", Cell 69:1067-1070 (1992)					
	4	41.	Murphy et al, "The potential role of NK versus-host disease after allogeneic bo					
42. Chavin, et al., "Anti-CD2 mAbs Suppress Cytotoxic Lymphocyte Activity by the Generation of Thi Suppressor Cells and Receptor Blockade," <i>J Immunol</i> 152:3729-3739 (1994)								
EXAMINER Maken Haddad DATE CONSIDERED 9/16/02								

INFORMATION DICKING IDE				CONSTINCT		TTY. DOCKET NO. -67689-3/RFT/RMS/RMK	SERIAL NO. 09/653,924		
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	PTO-1449					ILING DATE eptember 1, 2000	GROUP Not Yet Assigned		
		ОТ	HER DOCUM	IEN Sallpalading	Autl	thor, Title, Date, Per	rtinent Pages, Etc.)		
m t	+	43.	Pawelec, et al., CD4+ Human T	"Cytokine Modulation Cells," <i>Transplantati</i>	of Th	H1/TH2 Phenotype Differ (8):1095-1101 (1996)	entiation in Directly Alloresponsive		
	٤	44.	Halverson, et al Blood 90(5):208	I., "In Vitro Generation 39-2096 (1997)	n of Al	llospecific Human CD8+	T Cells of Tc1 and Tc2 Phenotype,'		
		45.	Tolerance Result 12(4)part 1, A61 Experimental Bi	ulting in Diminished G 14. Meeting Info: An iology. April 17-21 19	iraft-Vo nual N 999.	ersus-Host Disease in Vineeting of the Profession	uce CD4+ Alloantigen-Specific ivo," <i>FASEB Journal</i> (March 12, 1999) nal Research Scientists for		
		46.	Cytotoxic Activit	ty," J Immunology 14	8(11):	:3578-3582 (1992)	th Factor-Beta to Inhibit macrophage		
	Þ	47.	Diabetes and R 9:331-339 (199	tecurent Diabetes in S 6)	Synge	eneic Islet-Transplanted N	revents Spontaneous Autoimmune NOD Mice," Journal of Autoimmunity,		
	1	48.	Cytolytic Activity	y and Blunting of Inte	rferon	n Responsiveness," <i>J Im</i>	ions of Natural Killer Cells: Depressed munology 136(10):3916-3920 (1986)		
J		49.	Contrasting Effe	ects of Anti-CD2 and	Anti-C	CD3", <i>J Immunol</i> , 160:22	ells, IL-2 and NK Cell-Derived TGF-β: 248-2254 (1998)		
MH	<b>-</b>	50	Gray et al., "The between CD8+	e role of transforming T and NK cells", <i>J Ex</i>	grow op Med	oth factor beta in the general 2d 180:1937-1942 (1994)	eration of suppression: an interaction		
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EXAMI	NER	<u> </u>	Maker Ho	adderd	DATE	E CONSIDERED			